510(k) Summary

ICEPlex *C. difficile* Kit on the ICEPlex System

A. 510(K) NUMBER: K132726 Date Prepared: November 29, 2013

B. SUBMITTED BY (APPLICANT):

PrimeraDx
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NOV 2 9 2013

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C. PURPOSE OF SUBMISSION

Substantial equivalence determination of ICEPlex *C. difficile* Assay Kit on the ICEPlex® System for qualitative detection of the *C. difficile* toxin B gene (*tcdB* gene) in a human stool specimen in patients suspected of having *C. difficile* infection (CDI).

D. MEASURAND

Clostridium difficile toxin B gene (*tcdB*)

E. TYPE OF TEST:

Qualitative Nucleic Acid Amplification Test for *C. difficile* toxin B gene from liquid or soft tool specimen.

F. PROPRIETARY AND ESTABLISHED NAMES (TRADE NAMES)

Assay: ICEPlex *C. difficile* Assay

System: ICEPlex® System

G. REGULATORY INFORMATION

a. Regulatory Section:

21 CFR 866.3130 – *C. difficile* Nucleic Acid Amplification Test Assay

b. Classification:

Class II

c. Product Code

OZN, NSU

d. Panel

Microbiology (83)

H. INTENDED USE

a. Intended Use

The PrimeraDx ICEPlex® *C. difficile* Assay is for the qualitative detection of the *Clostridium difficile* toxin B gene (tcdB gene) in nucleic acids purified from unpreserved liquid or soft human stool specimens from patients suspected of having *C. difficile infection* (CDI).

The ICEPlex *C. difficile* Assay is intended to be used only on the ICEPlex® System, which integrates PCR-based amplification with capillary electrophoresis (CE) for the detection of amplification products. The assay is intended to aid in the diagnosis of CDI. Results should be considered in conjunction with patient clinical history.

b. Indication(s) for use

Same as Intended Use

c. Special Conditions for use statement(s)

For prescription use only

d. Special Instrument Requirement

ICEPlex® System

I. DEVICE DESCRIPTION

PrimeraDx's ICEPlex *C. difficile* Assay kit is intended to be used only on the ICEPlex System. The ICEPlex *C. difficile* Assay kit incorporates several universal features and approaches developed at PrimeraDx for the ICEPlex System. The ICEPlex *C. difficile* Assay kit includes a PCR enzyme and the appropriate PCR buffer system developed, optimized, verified and validated for ideal performance in multiplex PCR with subsequent capillary electrophoresis. The ICEPlex *C. difficile* assay kit includes a primer mix for detection of the *Clostridium difficile* toxin B gene (*tcdB* gene) in human stool specimen from patients suspected of having *C. difficile* infection (CDI). The ICEPlex *C. difficile* assay kit is comprised of a PCR enzyme, primer mix, PCR buffer, calibrators mix, injection buffer, internal control, and a positive control.

ICEPlex *C. difficile* Assay kit components

# of vials and volume	
2 vials, 1.5ml/vial	2x PCR Buffer P/N: 560-1001
1 vial, 45µl/vial	PCR Enzyme P/N: 560-1002
1 vial, 220µl/vial	25x Primer Mix P/N: 560-1003
1 vial, 220 µl/vial	25x Calibrators Mix P/N: 560-1004
1 vial, 100µl/vial	Positive Control P/N: 560-1005
3 vials, 1.5 ml/vial	10x Injection Buffer P/N: 560-1006
1 vial, 1.0 ml/vial	Internal Control P/N: 560-1007

The ICEPlex System combines two functional modules: an amplification module – PCR (Polymerase Chain Reaction) thermal cycler – and an analysis module – CE (Capillary Electrophoresis) system with fluorescent detection. Individual fluorescent PCR products from multiplexed PCR reactions are analyzed by CE through direct electrokinetic injection into the separating capillaries. The labeled amplicons are separated by size and the dyes are excited by two lasers within the system.

ICEPlex System Features

- Bench top instrument with PCR thermal cycler and integrated Capillary Electrophoresis (CE) system
- Two solid state lasers enabling fluorescent detection of dye-labeled PCR amplification products
- On-board reagents with liquid level sensing
- Touch screen software for easy, step-by-step processing of samples
- Ability to run multiple assays in the same plate
- Automated data analysis and result reporting
- Simultaneous detection and quantification of multiple DNA targets in the same reaction well.

J. SUBSTANTIAL EQUIVALENCE COMPARISON

a. PREDICATE DEVICE NAME

BD Max *C. diff* Assay

b. PREDICATE DEVICE 510(K) NUMBER

K130470

Comparison with Predicate Devices Showing Similarities

	PrimeraDx	Predicate:
	Similarities	
Intended Use	The PrimeraDx ICEPlex® *C. difficile* Assay is for the qualitative detection of the *Clostridium difficile* toxin B gene (*tcdB* gene) in nucleic acids purified from unpreserved liquid or soft human stool specimens from patients suspected of having *C. difficile* infection (CDI). The ICEPlex *C. difficile* Assay is intended to be used only on the ICEPlex® System, which integrates PCR-based amplification with capillary electrophoresis (CE) for the detection of amplification products. The assay is intended to aid in the diagnosis of CDI. Results should be considered in conjunction with patient clinical history.	The BD MAX *C. diff* Assay performed on the BD MAX System is an automated *in vitro* diagnostic test for the direct, qualitative detection of the *Clostridium difficile* toxin B gene (*tcdB*) in human liquid or soft stool specimens from patients suspected of having *C. difficile* infection (CDI). The test, performed directly on the specimen, utilizes real-time polymerase chain reaction (PCR) for the amplification of *C. difficile* toxin B gene DNA and fluorogenic target-specific hybridization probes for the detection of the amplified DNA. The BD MAX *C. diff* Assay is intended to aid in the diagnosis of CDI. **(Similar)**
Measurand	*Clostridium difficile* toxin B gene (*tcdB*)	Same
Specimen Type	Unformed (liquid or soft stool)	Same
Principle	DNA: real time PCR	Same

Comparison with Predicate Devices Showing Difference

	PrimeraDx (ICEPlex)	Predicate:
	Differences	
Instrument System	**ICEPlex System**	**BD Max System**
Detection/ Probes	Assays use real time PCR amplification with Capillary Electrophoresis and direct laser-induced fluorescent detection of target-specific labeled primers in optical channels.	Assay use PCR and amplified DNA targets are detected using hydrolysis (TaqMan) probes. Probes labeled flourophores are used to detect *tcdB*. Emitted fluorescent is measured in optical channels.
Sample Extraction	bioMérieux NucliSENS easyMAG	Integrated
Test Cartridge	Disposable single-use PCR plate and micro titer plate, and ICEPlex Cartridge with 48 Capillaries.	Disposable tray with reagents, microfluidics PCR chamber
Process	Extraction, PCR amplification, capillary electrophoresis, size- based target detection	Extraction, PCR amplification, in- sample optical detection based on hydrolysis probes.
Time to result	Four hours for 48 samples	Under 3 hours for 24 samples
Assay Controls	Calibration Control, Internal control. PCR Positive control provided. Negative control and Positive/Extraction Control provided by user	Sample processing control. User-provided Positive and negative controls are recommended
Results	Negative	Negative
	Positive	Positive
	Invalid, with error code	Unresolved - specimen failure
		Indeterminate - system failure with error code
		Incomplete Run - with error code

K. TEST PRINCIPLE

The ICEPlex *C. difficile* Assay on the ICEPlex System is a molecular diagnostic test for the qualitative detection of toxigenic *C. difficile* nucleic acids isolated and purified from liquid or soft stool specimens obtained from symptomatic patients. This test targets the *C. difficile* toxin B encoding gene (*tcdB*). The ICEPlex *C. difficile* Assay has been developed for use on the PrimeraDx ICEPlex System.

This instrument platform integrates PCR-based amplification with capillary electrophoresis (CE) based detection of amplification products. Oligonucleotide primers are designed to produce PCR products with unique CE mobility; enabling simultaneous measurement of multiple targets and controls in a single reaction. Each individual test includes three target sites of the *tcdB* gene (not reported separately), an Internal Control) and Calibrators. Calibrators of three sizes are used for aligning and assigning CE peaks, a procedure unique to the ICEPlex System. The ICEPlex C. *difficile* Assay is PCR based and is performed on nucleic acids purified from human stool sample. The ICEPlex C. *difficile* Assay is intended to be used only on the ICEPlex System.

To perform the test, liquid or soft stool is collected in a standard sterile container that can be sealed. Sample could be stored at 2-8°C for up to 48 hours prior to testing or frozen at -70°C or below if not processed within 48 hours. Sample extraction is performed using bioMérieux NucliSENS easyMAG™ System as per the ICEPlex *C. difficile* Assay instruction for use. PCR reagent master mix is prepared using a Primers mix, PCR enzyme, PCR buffer and calibrators. In a designated well of PCR plate, 40 µL of ICEPlex *C. difficile* Master Mix is aliquoted and 10 µL of extracted sample is added. Negative and positive controls are added in designated wells of the PCR plate. After the PCR plate is prepared, it is placed in the ICEPlex System to execute an instrument run for the detection of the *Clostridium difficile* toxin B gene (*tcdB* gene)per the user manual.

Assay Controls:

Controls provided with the ICEPlex *C. difficile* assay kit include:

Internal Control – Non-target nucleic acid that is co-extracted and co-amplified with the tcdB target. It controls for nucleic acid extraction efficiency, for the integrity of the reagents and for the presence of PCR

inhibitors in a given sample. The Internal Control needs to be spiked into each sample before extraction.

Calibration Control – A group of ICEPlex specific elements used to align electropherograms and assign identities of the target peaks. It also controls for the integrity of the kit reagents .

Positive Control - Non-infectious and non-contagious double stranded DNA containing fragment of the *C. difficile* tcdB gene.

Controls not provided with the ICEPlex *C. difficile* assay kit but required include:

Negative Control – Substitute S.T.A.R. buffer for the clinical specimen and process normally through the extraction system and on the ICEPlex Instrument.

Known Positive Sample - It is also required to include previously characterized positive sample or simulated sample with every easyMAG extraction run and include it in the subsequent ICEPlex Instrument run to verify successful lysis.

L. PERFORMANCE CHARACTERISTICS

a. ANALYTICAL PERFORMANCE

Precision

The ICEPlex *C. difficile* Assay Precision Study was performed on a panel of samples prepared by spiking an appropriate amount of *C. difficile* culture isolate from ATCC strain BAA-1805 into a pooled clinical negative stool matrix. The panel members included:

- Low positive
- Moderately positive
- Negative sample
- (C20-80) sample.

Runs for this study also include the following controls:

- Negative Control
- Positive Control

The precision study consisted of two operators; three lots of ICEPlex *C. difficile* Assay kits; and three ICEPlex instruments. The precision study was

run over 12 non-consecutive days with two runs per day and two replicates of each sample per run. One negative sample (out of a total of 144 observations) and one low positive sample (out of a total of 144 observations) produced invalid results during the study.

Precision Study Overall Results

Concentration	Overall Agreement		Ct Value		
			Mean Ct	SD	%CV
Negative	143/143	100%	N/A	N/A	N/A
Low Positive	142/143	99%	30.6	1.4	4.5
Moderate Positive	144/144	100%	28.7	0.8	2.7
Hi/Low (C20-80)	105/144	73%	34.6	2.1	6.2

Reproducibility

Reproducibility of the ICEPlex *C. difficile* Assay was evaluated at 3 independent laboratory sites. The reproducibility study panel included 4 simulated samples – moderate positive (expected positive 100% of the time), low positive (near assay limit of detection, expected positive >95% of the time), negative (expected negative 100% of the time) and C20-80, (expected positive 20-80% of the time). The panel also included positive and negative controls. Panel samples were tested at each independent laboratory site for 5 days with 2 runs per day and 3 replicates of each panel member per run. One low positive sample (out of a total of 90 observations) and one moderate positive sample (out of a total of 90 observations) produced invalid results during the study Study results are summarized in the tables below:

Reproducibility Study Result – Overall Agreement

	Observed	Total	% Agreement	95% CI
C20-80*	62/90	90	69	58.26 to 78.23
Moderate Positive	89/89	89	100	95.98 to 100
Low Positive	89/89	89	100	95.98 to 100
Negative	90/90	90	100	95.98 to 100
Negative control	60/60	60	100	94.04 to 100
Positive control	60/60	60	100	94.04 to 100

NOTE: *For C20-80 samples % agreement is given as % positive results

Reproducibility Study, Site to Site % Agreement

	Site A			Site B			Site C		
	Observed	Total	% Agreement	Observed	Total	% Agreement	Observed	Total	% Agreement
C20-80*	23	30	77	23	30	77	16	30	53
Moderate Positive	30	30	100	30	30	100	29	29	100
Low Positive	30	30	100	29	29	100	30	30	100
Negative	30	30	100	30	30	100	30	30	100
Negative Control	20	20	100	20	20	100	20	20	100
Positive Control	20	20	100	20	20	100	20	20	100

Analytical Sensitivity (Limit of Detection)

Analytical sensitivity of the ICEPlex *C. difficile* Assay was determined using a 2-fold serial dilution of two *C. difficile* strains that were spiked into qualified negative stool and processed according to ICEPlex *C. difficile* Assay Instructions for Use. 20 replicates at each concentration level were tested on 3 different ICEPlex instruments. Analytical sensitivity of the assay was defined as the lowest concentration at which at least 95% of all replicates were reported positive.

LOD of the ICEPlex *C. difficile* assay determined for:

- *C. difficile* strain 43255 (630) (Toxinotype 0): 8CFU/rxn
- *C. difficile* strain BAA-1805 (Toxinotype III): 2CFU/rxn

Analytical Reactivity (Inclusivity)

To assess the analytical inclusivity of the ICEPlex *C. difficile* Assay, a set of 20 additional toxigenic strains of *C. difficile* were spiked into negative matrix (pool of negative clinical samples) at a level approximately three times above the assay LOD. Spiked samples were processed in accordance with the ICEPlex *C. difficile* Assay Instructions for Use. The results of the study are as follows:

Strain	Toxinotype	Result
BAA-1382 (630)	A+B+	Positive
BAA-1871 (4111)	0, A+B+binary-, NAP5	Positive
9689 (90556-M6S)	0	Positive
700792 (14797-2)	A+B+	Positive
BAA-1875 (5325)	V, A+B+, NAP7	Positive
51695 (BDMS 18 AN)	A+B+	Positive
43598 (1470)	VIII, A-B+	Positive
43600 (2149)	A+B+	Positive
43599(2022)	A+B+	Positive
43597	A+B+	Positive
43594 (W1194)	A+B+	Positive
43596 (545)	I, A+B+	Positive
17858 (1253)	A+B+	Positive
17857 (870)	A+B+	Positive
BAA-1808	A+B+	Positive
BAA-1806	A+B+	Positive
BAA-1803	III A+B+, NAP1	Positive
BAA-1870 (4118)	III, binary+, NAP1	Positive
BAA-1873 (5283)	0, A+,B+,binary-	Positive

Note: Strain BAA-1814 (Toxinotype XXII) was determined to be non-viable. PrimeraDx cannot claim inclusivity to this strain

Analytical Specificity

Cross Reactivity

A microbial cross reactivity study was performed with the ICEPlex *C. difficile* Assay using a panel of samples, consisting of pooled negative clinical matrix. spiked with 5 non-toxigenic *C. difficile* strains, 14 other *Clostridium* strains or 54 other pathogens or representatives of healthy intestinal flora. Bacteria and parasites were tested at concentrations $1x10^7$ organisms/ml, viruses at concentrations $1x10^{5.5}$ - $1x10^6$ TCID50/ml. In this study, *Clostridium sordellii* was identified as cross-reacting, due to high toxin sequence similarity. *Clostridium sordellii* is not typically found in GI tract. Reactivity with this organism has little to no clinical significance. One of three replicates for *Clostridium difficile* strain 43601 was reported positive at 14 cps/rxn just above the assay cutoff set at 12 cps/rxn. PrimeraDx was not able to verify interference to this strain in follow-up analysis. None of other species resulted in positive result with ICEPlex *C. difficile* Assay.

Interfering Substances

A chemical interference study was performed using a panel of samples, consisting of pooled negative clinical matrix and contrived samples produced by supplementing pooled negative clinical matrix with culture stock of two *C. difficile* strains, ATCC BAA-1805 and 43255, added to produce samples resulting in 9 and 21 cfu/rxn, respectively (approximately three times the assay LOD). The table below shows potential interfering substances and concentrations used in this study.

Substance	Active Ingredient	Concentration
Anti-Fungal /Anti-Itch Vaginal	Nystatin	1% (w/v)
Creams/Ointments/Suppositories	Hydrocortisone	1% (w/v)
Anti-Hemorrhoid Creams/Ointments	Phenylephrine	1% (w/v)
Antacids	Calcium Carbonate/ Aluminum Hydroxide/ Magnesium Hydroxide	10% (w/v)
Enemas	Mesalazine/Mineral Oil	10% (w/v)
Condoms with Spermicidal Lubricant	Nonoxynol-9	1% (w/v)
Anti-Diarrheal Medication	Loperamide Hydrochloride/ Bismuth Subsalicylate	10% (w/v)
Laxatives	Sennosides	1% (w/v)
Antibiotic	Metronidazole	12.5mg/ml
Antibiotic	Vancomycin	12.5mg/ml
Non-Steroidal Anti-Inflammatory Medications	Naproxen Sodium	12.5mg/ml
Moist Towelettes	Benzalkonium Chloride, Ethanol	0.1% (v/v), 1%(v/v)
Fecal Fat	Lipids, etc.	40% w/v
Whole Blood	Glucose, Hormones, Enzymes, Ions, Iron, etc.	40% v/v
Mucus	Mucin protein	3.5% (w/v)

None of the substances interfered with detection of *C. difficile* from both tested strains or caused a false positive result in the negative samples.

Well-to-well Cross Contamination and Run-to-run Carryover Contamination

Samples for Well-to-well Cross Contamination and Run-to-run Carryover Contamination study were prepared by the extraction of a series of high positive samples (with analyte concentration exceeding the concentration found in 95% positive samples in the intended use population) alternating with negative samples. Location of positive and negative samples on the extraction instrument was altered

run-to-run. On the ICEPlex system, high positive and negative samples were run in a checkerboard fashion. In the consecutive run, the platemap was inverted to allow wells and capillaries that were running negative samples to run positive samples. The study included 6 runs: each run had 24 high positive and 24 negative samples. The study identified no contamination in the negative samples run in the course of the study, reporting False Positive rate at 0% (0 False Positives out of 141 valid negatives). These data allowed PrimeraDx to conclude that there was no well-to-well Cross Contamination or run-to-run Carryover Contamination observed in the course of this study.

b. CLINICAL PERFORMANCE STUDIES

A clinical study was conducted at three independent sites to compare performance of the ICEPlex *C. difficile* Assay Kit on the ICEPlex System to toxigenic *C. difficile* direct culture.

This study protocol directed the laboratory testing of specimens from patients suspected of gastrointestinal tract infection with a toxigenic strain of *Clostridium difficile* bacteria. Each of the sites performed testing in the ICEPlex *C. difficile* Assay on specimens collected at the site. These specimens collected from all three sites were tested by toxigenic *C. difficile* direct culture. A total of 1103 (806 fresh, 297 frozen) samples were collected and enrolled in the investigational study at 3 clinical sites. 97 frozen samples were excluded from the analysis due to improper storage conditions and temperature excursions. An additional 37 samples were excluded due to study protocol deviations.

969 specimens were compliant and met all protocol requirements. 952 (98.2%) out of 969 gave reportable results and were included in the statistical analysis. 17 samples remained invalid upon retest (1.8% of all analyzed samples). 3 out of the 17 unresolved invalids were reported positive by direct culture.

Performance characteristics determined in the course of this study were as follows. The Clopper-Pearson exact method was used to calculate confidence intervals.

Overall Results

		Direct Culture	
		Positive	Negative
ICEPlex C. difficile Assay	Positive	153	20[a]
	Negative	17[b]	762
	Total:	170	782

Positive Percent Agreement (95% CI): 90.0% (84.5 - 94.1)
Negative Percent Agreement (95% CI): 97.4% (96.1 - 98.4)

Notes:

Discordant testing was performed for samples where ICEPlex *C. difficile* Assay and toxigenic *C. difficile* direct culture reported results in disagreement.

Discordant analysis included microbiological isolation of and PCR targeting of 3 appropriate regions of the toxin B gene (Different recognition sites than the ones used in the ICEPlex *C. difficile* assay) with bi-directional DNA sequencing.

[a]6 of 20 reported positive by ICEPlex *C. difficile* Assay were reported positive by discordant analysis.
[b]14 of 17 reported negative by ICEPlex *C. difficile* Assay samples were reported positive by discordant analysis.

Results by Site

	Site A	Site B	Site C
PPA (95% CI)	49/ 55 = 89.1% (77.8 - 95.9)	56/ 64 = 87.5% (76.8 - 94.4)	48/ 51 = 94.1% (83.8 - 98.8)
NPA (95% CI)	281/ 288 = 97.6% (95.1 - 99.0)	256/ 262 = 97.7% (95.1 - 99.2)	225/ 232 = 97.0% (93.9 - 98.8)

M. CONCLUSION

PrimeraDx believes that based on the clinical and analytical performance comparison data, ICEPlex *C. difficile* Assay on the ICEPlex System is substantially equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

PRIMERADX, INC.
FAYYAZ MEMON
VP, REGULATORY AFFAIRS AND QUALITY ASSURANCE
171 FORBES BLVD
SUITE 1000
MANSFIELD MA 02048

November 29, 2013

Re: K132726
Trade/Device Name: ICEPlex *C. difficile* Assay Kit, ICEPlex System
Regulation Number: 21 CFR § 866.3130
Regulation Name: *Clostridium difficile* toxin gene amplification assay
Regulatory Class: II
Product Code: OZN, NSU
Dated: September 6, 2013
Received: September 9, 2013

Dear Mr. Memon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809). please contact the Division of Small Manufacturers. International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also. please note the regulation entitled. "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803). please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers. International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours.

Uwe Scherf -S for

Sally A. Hojvat. M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132726

Device Name: ICEPlex®*C. difficile* Assay on the ICEPlex® System

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Ribhi Shawar -S
2013.11.29 08:11:08 -05'00'

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)